LDL Cholesterol (Direct) Test Kit

REF	Pack Size	Reagent 1	Reagent 2	Reagent 3
LDLLMS01	1×40 ml	1×30 ml	1×10 ml	1x1 ml
LDLLMS02	2×40 ml	2×30 ml	2×10 ml	1x1 ml

INTENDED USE
Quantitative determination of Direct LDL Cholesterol in serum/ plasma Only for In Vitro Diagnostic use.

CLINICAL SIGNIFICANCE
Numerous clinical studies have shown that the different lipoprotein classes have varied effects. The studies all point to LDL cholesterol as the key factor in the pathogenesis of artherosclerosis and CAD, while HDL cholesterol has often been observed to have protective effect. Even within the normal range of total cholesterol concentrations, an increase in LDL cholesterol can occur with an associated risk for CAD.

METHOD: Direct Selective Inhibition Method

TEST PRINCIPLE
In the cholesterol determination system with the presence of cholesterol lipase (CHER) and cholesterol oxidase (CHOD), a specific surfactant is added to selectively dissolve LDL-C to measure LDL-C. Other lipoprotein (HDL, VLDL, chylomicrons) does not react due to being hindered by surfactants and saccharides, and remain in the form of lipoprotein in the reaction system. based on this principle, LDL-C can be measured.

$$\text{Cholesterol esters} + H_2O \xrightarrow[\text{Cholesterol esterase}]{} \text{Cholesterol} + \text{Fatty acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow[\text{Cholesterol oxidase}]{} \text{Cholestenol} + 4H_2O_2$$

$$H_2O_2 + \text{4-AA} + \text{HDAOS} \xrightarrow[\text{Peroxidase}]{} \text{Benzoquinone} + 5H_2O$$

KIT CONTENTS /COMPONENTS
Reagent 1: Buffer Reagent
Reagent 2: Substrate Reagent
LDL Cholesterol Calibrator: Concentration printed on vial.

MATERIAL REQUIRED BUT NOT PROVODED
Laboratory instrumentation, spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi-automated, calibrated micropipettes, glass or high-quality polystyrene cuvettes, test tubes/rack, heating bath, controls, blood mixer & saline.

SAFETY PRECAUTIONS AND WARNINGS
1.Storage conditions as mentioned on the kit to be adhered.
2.Do not freeze or expose the reagent to high temperature as it may affect the performance of the kit.
3.Before the assay bring all the reagents to room temperature.
4.Avoid contamination of the reagent during assay process.
5.Use clean glassware free from dust or debris.

REAGENT PREPARATION, STORAGE AND STABILITY
Reagent 1 & Reagent 2 are ready to use and are stable up to the expiry date stated on the label.
Add 1 ml Distilled water to dissolve the content in vial, stable for 7 days at 2 – 8°C

REAGENT DETERIORATION
Do not use reagents after the expiration date printed on the reagent label. Avoid thawing and freezing of aliquoted calibrator and lipid control.

PROGRAM

Reaction Mode	End point
Primary Wavelength	578 nm
Secondary Wavelength	670 nm
Light Path	10 mm
Blanking	Reagent Blank
Reagent Volume	600 µl
Calibrator Volume	6µl
Sample Volume	6µl
Incubation	5+5 mins
Calibrator Concentration	Printed on vial
Linearity	700 mg/dL

PROCEDURE

	Blank	Calibrator	Sample
Reagent 1	450 µl	450 µl	450 µl
Calibrator	----	6 µl	----
Sample	----	----	6 µl
Mix well and incubate for 5mins at 37°c, then add			
Reagent 2	150 µl	150 µl	150 µl

Mix and incubate for 5 min at 37°C.Measure the absorbance of calibrator and sample against reagent blank.

CALCULATION

$$\text{LDL-C (mg/dl)} = \frac{\text{OD of sample}}{\text{OD of calibrator}} \times \text{Conc. Of Calibrator}$$

NORMAL VALUE
≤130 mg/dl

LIMITATIONS
If the value exceeds 700 mg/dl, dilute the sample with 0.9% saline solution rerun and result multiplied by dilution factor.

QUALITY CONTROL AND CALIBRATION
It is recommended to perform internal quality control with assayed normal and assayed abnormal, to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator or the Standard included, calibrate the assay.
1.When using a new reagent or lot
2.When QC values are out of range
It is recommended that each laboratory should assign its own normal range.

WASTE DISPOSAL
This Product is made to be used in professional laboratories.

HIGHLIGHT
1.The Reagents are sensitive to light & higher temperature. Reagents may develop a slight yellow coloration on ageing which does not interfere with the functionality of reagent.
2.If the volume of the reagent is not sufficient to fill the cuvette, double all the specified volumes.
3.Storage condition mentioned on the kit is to be maintained.
4.Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
5.Before testing bring the reagents to the specified temperature.
6.Avoid reagents contamination.
7.Every time use new pipette-tips for pipetting out the reagents.
8.These Reagent kits meant for laboratory / professional use only, not for Drug use.

REFERENCES

1.Natio H.K., et Al, CLIN Chem, 41:132-133,1995
2.Seidel D., etal, Internist,28:606-314,1987
3.Weiland H. and Seidel D., J Lip Res,24:904-909,1983
4.Friedwald W.F.,et al,Clin Chem,18:499-502,1972.
Lords Data File.

REF	Catalog No.	Σ	Contain Sufficient for test
LOT	Batch No.		Instruction for use
	Manufacturing Date	IVD	*In-vitro* Diagnostics
	Expiry Date		Storage temperature
	Manufacturer		

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